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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,139	05/19/2006	Leon Rudakov	077567-0021	9222

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,139	RUDAKOV ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 5/19/2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The provisional restriction made on a telephone conversation with Todd Hales on January 29, 2008 with respect to an election made without traverse to prosecute claims 1-34 and 38 is withdrawn. Upon further consideration by the examiner, the restriction was withdrawn and all claims were considered.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
>
> It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Claim Objections

2. Claim 8 is objected to because of the following informalities: on the first line, "the biodegradable material" should be --the polymeric material or the biodegradable material--. Claim 8 depends on claim 7 which gives an option of a polymeric of a biodegradable material therefore claim 8 should contain both options. Appropriate correction is required.

3. Claim 30 is objected to because of the following informalities: on the first line, "reagent" should be –drug or reagent--. Claim 30 depends on claim 8 which gives an

option of a drug or reagent therefore claim 30 should contain both options .

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 14 and 15 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Claim 14 is dependent on claim 1 which states that the membrane is permeable and porous therefore it cannot be non-permeable and non-porous.

6. Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. An aneurysm which is a cardiovascular disease cannot be patented since it is a composition of matter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 4, 6-11, 19, 24-27, 30, 31, and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudakov et al (6,451,050).

Rudakov discloses the following claimed limitations:

Claim 1: A medical device (11) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (16) expandable from a first position to a second position (Col. 5 Lines 15-17), said mechanically expandable device (16) is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel (Col. 5 Lines 13-17). The mechanically expandable device (16) is engaging through the vessel by expanding radially and providing the rigidity on the top sleeve (13) in order to maintain contact with the vessel. Furthermore Rudakov discloses that a membrane expandable (12, 13) from a first position to a second position in response to expansion of said mechanically expandable device (16) (Col. 5 Lines 15-17), said membrane (12, 13) being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane), and at least a portion of the membrane (12, 13) is secured to the mechanically expandable device (16) to maintain the position of the membrane (12, 13) relative to the mechanically expandable device (16) when expanded to the second position (the membrane is attached to the mechanically expandable device by using rings 17 and by everting the membrane in order to hold the mechanical expandable device as disclosed in the Col. 3 Lines 48-65); wherein the membrane (12, 13) is permeable (it can be penetrated, especially by liquids or gases, depending on the size of the pores, such as drug agents) and porous (Col. 2

Line 16), the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented. The size of the pours allow for drugs and agents to pass to the aneurysm put it does not allow blood since the pore holes are only big enough to promote cell growth and drug transmission.

Claim 3: That the membrane (12, 13) is made of a biocompatible and elastomeric polymer (Col. 2 Lines 10-21).

Claim 4: That the membrane (12, 13) has a thickness of about 0.0005 to 0.005" (Col. 2 Lines 22-25).

Claim 6: That the membrane (12, 13) has pores between 20 to 100 microns in size (Col. 2 Lines 28-29).

Claim 7: That the membrane (12, 13) is made from polymeric material (Col. 2 Lines 10-13).

Claim 8: That the polymeric material forms multiple sub-layers mixed with drugs or reagents (Col. 3 Lines 26-29 and Col. 4 Lines 41-43 and Lines 58-61). The layers are formed by each of the coatings on the membrane.

Claim 9: That the membrane (12, 13) is capable of isotropic expansion (Col. 5 Lines 13-17).

Claim 10: That the membrane (13) is disposed on the exterior surface of the device (16) (Col. 2 Lines 4-5 and Fig. 1).

Claim 11: That the membrane (12, 13) completely surrounds the device (Col. 3 Lines 52-58). There is only one material use to form the outer membrane (13) and the inner membrane (12) which surrounds the device (16) as disclosed in the method of manufacturing in Col. 3 Lines 42-67.

Claim 19: That the membrane (12, 13) comprises a plurality of polymeric strips (17) (Col. 2 Lines 55-58) secured to the mechanically expandable device (16) (Col. 2 Lines 5-6 and 63-64).

Claim 24: That the mechanically expandable device (16) comprises a generally tubular structure (Fig. 1) having an exterior surface defined by a plurality of interconnected struts (26 with 22 and 23) having interstitial spaces therebetween (Fig. 1).

Claim 25: The mechanically expandable (16) device is balloon expandable (Col. 5 Lines 13-17).

Claim 26: That the mechanically expandable device (16) is a stent (Fig. 1). Figure 1 shows that the expandable device (16) has the structure of a stent as well as Rudakov discloses that the final product is a stent-graft where the expandable device (16) is the stent and the graft is the membrane (12, 13).

Claim 27: That the membrane (12, 13) is supported by the generally tubular structure (Fig. 1) and is attached to at least one strut (26) as seen in Fig. 1-3 as well as in the explanation of the manufacturing process (Col. 4Lines 1-14) where the membrane (12, 13) are placed on the expandable device (16).

Claim 30: That the at least one drug or reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder (Col. 4 Lines 36-49).

Claim 31: That at least one radiopaque marker is provided on the mechanically expandable device (16) to improve visibility of the device during and after insertion (Col. 4 Lines 17-21).

Claim 35 and 36: A method of manufacturing comprising: disposing the generally tubular structure on a mandrel (51); and disposing the membrane (12,13) onto the outer surface of the mechanically expandable device (16). The device has two membranes, where the first membrane (12) is first disposed on the mandrel (51) and then the expandable device/stent (16) is placed on the mandrel as well as the connecting rings (17). After this part the membrane (13) is placed on top of the mechanically expandable device/stent as it is disclosed in Fig. 3-4 and Col. 4 Lines 1-14.

Claim 37: That the method of disposing is adhesion (Col. 2 Lines 60-64).

Claim 38: That the stent (16) is delivered to the aneurysm by a delivery catheter (Col. 5 Lines 5-9).

9. Claims 1, 2, 5, 12, 13, 16-21, 26, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Solovay (5,769,884).

Claim 1: A medical device (10) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (20) expandable from a first position to a second position (Col. 3 Line 44), said mechanically expandable device (20) is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel (16) so as to maintain a fluid pathway through said vessel (Col. 3 Lines 50-59). Figure 4 shows how the expandable device (20) is in contact with the vessel (16).

Furthermore it is disclosed that a membrane expandable (30) from a first position to a second position in response to expansion of said mechanically expandable device (20) (Fig. 3-4 where the device is expanded), said membrane (30) being positioned proximal to the aneurysm (15) and obstructing blood circulation to the aneurysm (15) when expanded to the second position (Fig. 3-4), and at least a portion of the membrane (30) is secured to the mechanically expandable device (20) to maintain the position of the membrane (30) relative to the mechanically expandable device (20) when expanded to the second position (Col. 3 Lines 45-50); wherein the membrane (30) is permeable (it can be penetrated, especially by liquids or gases, depending on the size of the pores, such as drug agents) and porous (Col. 3 Line 45-46), the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented (Col. 2 Lines 1-9).

Claim 2: That the distance between adjacent pores is from about 40 to 100 microns (Col. 2 Lines 51-55 and Col. 5 Lines 51-53). The pore size is between 30-120 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7) therefore the space between the pores is in the specified range. For example if the pore size is 30 microns than the space between the pores can be 90 microns.

Claim 5: That the ratio of the material surface area of the membrane (30) is from about 25 to 75%. Do to the size of the pores and the space between the pores the surface area of the membrane is between that range. For example if the membrane has pores

spaced close together like the one shown in Fig. 6 section 12 it can be seen that if the pore size were 30 microns and the space between them were 15 microns the surface area would be around 30%-50%.

Claim 12: That the membrane (30) circumferentially surrounds a portion of the device (Col. 3 Lines 45-48 and Fig. 7). Figure 7 shows that the membrane is tubular.

Claim 13: That the membrane (30) covers a portion of the device. The membrane contains pores such as the ones seen in Fig. 6, therefore the membrane (30) covers portions of the expandable device while leaving pores (gaps) around the device.

Claim 16: That the membrane has fabricated pores (Col. 7 Lines 45-48) between 20 to 100 microns in size (Col. 2 Lines 34-35 and Col. 5 Lines 5-7).

Claim 17: That the pores are fabricated by laser drilling (Col. 7 Lines 48-49).

Claim 18: That the distance between the pores is less than 100 microns. (Col. 2 Lines 51-55 and Col. 5 Lines 51-53). The pore size is between 30-120 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7) therefore the space between the pores is in the specified range. For example if the pore size is 30 microns than the space between the pores can be 90 microns.

Claim 19: That the membrane (30) comprises a plurality of polymeric strips (the fiber disclosed in Col. 7 Lines 15-16) secured to the mechanically expandable device (20) (Col. 7 Lines 45-48).

Claim 20: That the strips (the fiber) are less than 0.075 mm (Col. 7 Lines 15-18) and the distance between adjacent strips (fibers) is less than 100 microns. There are strips that are grouped together which will have a distance of less than 100 microns,

furthermore the strips are interlaced forming the pores which are around 30-120 microns. So the distance from one strip is less than 100 microns.

Claim 21: That the membrane comprises a mesh secured to the mechanically expandable device (20). The mesh is the membrane (30) which is braided which forms a mesh structure (Col. 3 Lines 45-48).

Claim 26: That the mechanically expandable device (20) is a stent (Col. 3 Line 44).

Claim 28: That the membrane (30) is tubular (Col. 7 Lines 13-15 and Col. 3 Lines 46-48) having a diameter similar to a nominal initial diameter of the stent (20) (the diameter has to be similar to that of the stent since it is adhered onto the stent) and wherein the membrane (30) is disposed onto the outer surface of the stent (20) (Col. 7 Lines 25-26 and Col. 3 Lines 45-48).

Claim 29: That the membrane (30) is a segment of a tubular structure (Col. 7 Lines 13-15) disposed onto a portion of the outer surface of the stent (Col. 7 Lines 25 -26 and Fig. 1-4).

10. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Dereume et al. (5,948,018).

Dereume discloses a medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising: a first mechanically expandable device (57) for inserting into a first vessel (the central mechanical structure which is the first one to be deployed as seen in Fig. 10); a second mechanically expandable device (55, 56) for inserting into a second vessel (55 is the second expandable member to expand as can be seen in Fig. 11 and 56 is the last

expandable member to be expanded as seen in Fig. 13); each mechanically expandable device (55, 56, 57) expandable from a first position to a second position (Fig. 9-13), said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel (Fig. 9-13). The mechanically expandable devices are engaging through the vessel by expanding radially and providing the rigidity on the top membrane in order to maintain contact with the vessel.

Furthermore Dereume discloses a membrane (53, 54) expandable from a first position to a second position in response to expansion of said mechanically expandable devices (Col. 7 Lines 50-55 and Fig. 7-13), said membrane being positioned proximal to the aneurysm and obstructing blood circulation to the aneurysm when expanded to the second position (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane), and at least a portion of the membrane (53, 57) is secured to each mechanically expandable device (Col. 7 Lines 58-60) to maintain the position of the membrane relative to the mechanically expandable devices when expanded to the second position (Fig. 9-13); wherein the membrane is permeable (it can be penetrated, especially by liquids or gases, depending on the size of the pores, such as drug agents) and porous (Claim 1 and 18) , the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain

arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented. The size of the pours allow for drugs and agents to pass to the aneurysm put it does not allow blood since the pore holes are only big enough to promote cell growth and drug transmission.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884).

Solovay discloses that the spaces (the pores) of the mesh (30) are less than 100 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7).

Solovay discloses the claimed invention except that the width of the meshing is between 0.025 to 0.050 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width of the meshing be between 0.025 to 0.050 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Claim 32-33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Dereume et al. (5,639,278).

Claim 32:

Rudakov teaches all the claimed limitations discussed above however, Rudakov does not disclose that at least one radiopaque marker is made from gold or platinum.

Dereume discloses that at least one radiopaque marker is made from gold or platinum (Col. 14 Lines 44-46).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov with a radiopaque marker made of gold or platinum in view of the teachings of Dereume, since this materials are well known in the art to be used as radiopaque markers.

Claim 33:

Rudakov discloses that there is a radiopaque marker at the end of teh expandable device (Col. 4 Lines 17-19).

Rudakov teaches all the claimed limitations discussed above however, Rudakov does not disclose that there is radiopaque marker at the center of the expandable device.

Dereume discloses that there is radiopaque marker at the center of the expandable device (Col. 14 Lines 38-44). The radiopaque marker is placed in the bifurcation area which is at the center of the mechanical expandable device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov with a radiopaque marker at the center of the device in view of the teachings of Dereume, in order to provide visualization of the graft and specifically of the area where the bifurcation or aneurysm is located.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER